

## US approves diabetes drug with new approach (Update)

January 8 2014, by Matthew Perrone

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The U.S. Food and Drug Administration on Wednesday approved a new diabetes drug from Bristol-Myers Squibb and AstraZeneca that uses a novel approach to reduce blood sugar.

Farxiga is a once-a-day tablet designed to help diabetes patients eliminate excess sugar via their urine. That differs from older drugs that decrease the amount of sugar absorbed from food and stored in the liver.

The drug is the second product approved in the U.S. from the new class of medicines known as SGLT2 drugs. In March the FDA approved Johnson & Johnson's Invokana, which also works by eliminating excess sugar through patients' urine.

The agency cleared Farxiga tablets for patients with type 2 diabetes. The approval marks a comeback for the drug, which was previously rejected last year after studies raised concerns about links to bladder cancer and liver toxicity.

Ten cases of bladder cancer were found in patients taking the drug in clinical trials, so Farxiga's label warns against using it in patients with the disease. A panel of FDA advisers last month said that the uptick in cancers was likely a statistical fluke, and not related to the drug. But the FDA is requiring Bristol and AstraZeneca to track rates of bladder cancer in patients enrolled in a long-term follow up study. The companies will also monitor rates of heart disease, a frequent safety issue with newer diabetes medications.

The most common side effects associated with Farxiga included fungal and urinary tract infections. The drug can be used as a stand-alone drug or in combination with other common diabetes treatments, such as insulin and metformin.

People with type 2 diabetes are unable to properly break down carbohydrates, either because their bodies do not produce enough insulin or have become resistant to the hormone, which controls blood sugar levels. Diabetics often require multiple drugs with different mechanisms of action to control their blood sugar levels.

New York-based Bristol-Myers Squibb Co. and London-based AstraZeneca PLC already co-market the diabetes drug Onglyza, which increases insulin production while reducing glucose production.

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